

**REMARKS**

The Office Action of November 30, 2001 presents the examination of claims 1-6. Claims 1 and 6 are amended. No new matter is inserted into the application.

***Rejection under 35 U.S.C. § 103(a)***

The Examiner maintains the rejection of claims 1-6 under 35 U.S.C. §103(a), for allegedly being obvious over the combination of Lindberg et al. (*Pharmacology & Toxicology*) in view of Clerico et al. (*Clinical Chemistry*). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The present invention relates to a method for the measurement of the mammalian natriuretic peptide using containers made of or coated with a material, wherein said material, which is selected from silicone or plastics, does not convert an inactive form of substances degrading the mammalian natriuretic peptide into an active form. In other words, the containers inhibit the activation of natriuretic peptides degrading substances.

Lindberg et al. fails to state that the containers inhibit the activation of substances degrading ANP. Lindberg et al. merely discloses on page 281 column 1, third paragraph, that a sample of ANP may result in a falsely low value if handled within glass or plastic containers. On page 278, Fig. 4, it is shown that the

degradation of ANP is not significant between the silicone-coated containers and others. Moreover, on page 281, column 1, fourth paragraph, adsorption of ANP can easily be avoided by the addition of HAS (Human serum albumin). Accordingly, addition of HAS decreases adsorption of ANP to the containers. In other words, Lindberg et al. discloses that the greatest recovery of ANP is achieved by an addition of HAS but not by an inherent property possessed by containers.

The present invention differs from Lindberg et al. in that it is directed to a method for inhibiting the activation of substances that degrade peptides. Lindberg et al., on the other hand, is directed to substances, e.g. HAS, that inhibit adsorption of ANP, wherein the containers are used only for the preparation of ANP samples.

Clerico et al. teaches on page 1631, column 2, last paragraph, that ANP is degraded by plasma protease and ANP receptors. Thus, degradation of ANP can avoid the need to separate plasma from a blood sample and to store at low temperatures based upon the addition of protease inhibitors.

As mentioned above, Lindberg et al. does not disclose containers for holding ANP, but merely substances, e.g. HAS, for avoiding the adsorption of ANP. Therefore, contrary to the Examiner's assertions, Lindberg et al. shows that the containers

that they do use, don't work. Thus, the lack of degradation is not an inherent property possessed by the containers.

Further, regarding the Examiner's assertions that it would be obvious to combine the disclosures of prior art references, Applicants respectfully disagree because there is no motivation to combine the two references. Lindberg only teaches that ANP may have a falsely low value if handled within glass or plastic containers. Accordingly, Applicants submit that it would not have been obvious to one of ordinary skill in the art at the time invention was made to employ the containers described in Lindberg et al. to store ANP-containing specimens as shown by Clerico. The Examiner is using improper hindsight reconstruction to combine the disclosures of Lindberg et al. and Clerico et al.

For the above reasons, the instant rejection is improper and should be withdrawn.

***Rejection under 35 U.S.C. § 112, second paragraph***

The Examiner rejects claims 1-6 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the term "a material" is indefinite because the specific material or substance used in the claim is not definitively set forth. In response to the

Examiner's remarks, Applicants amend claims 1 and 6 to recite that the "material" is selected from the group consisting of silicone and plastics. Support for this amendment is found in the specification, such as on page 2, lines 23-29 to page 3, line 1.

Applicants respectfully submit that the above amendment renders the instant claims in full compliance with 35 U.S.C. § 112, second paragraph. Thus, Applicants respectfully request that the instant rejection be withdrawn.

#### ***Title***

The Examiner states a new, more descriptive title is required. In response to the Examiner's remarks, Applicants amend the title accordingly. Thus, the instant objection is overcome.

#### ***Summary***

All of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.


If there are any minor matters precluding allowance of the present application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

1. (Three Times Amended) A method for inhibiting the degradation of mammalian natriuretic peptides in a specimen, comprising:

placing the specimen into a container, wherein the face coming into contact with the specimen is made of or coated with a material,

wherein said material inhibits the activation of a substance,  
which substance if not activated, cannot degrade the mammalian natriuretic peptides and is selected from the group consisting of silicone and plastics.

6. (Twice Amended) A method for measuring mammalian natriuretic peptides in a specimen, comprising the steps of:

employing a container, upon handling the specimen, comprising a material, wherein said material inhibits the activation of a substance, which substance if not activated, cannot degrade the mammalian natriuretic peptides and is selected from silicone or plastics; and

measuring the mammalian natriuretic peptides by standard means.